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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,793	11/18/2003	Debbie Yaver	10351.200-US	8797
25907	7590	05/04/2007		
NOVOZYMES, INC. 1445 DREW AVE DAVIS, CA 95616			EXAMINER JOIKE, MICHELE K	
			ART UNIT	PAPER NUMBER
			1636	
			MAIL DATE	DELIVERY MODE
			05/04/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/716,793		YAYER ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Michele K. Joike, Ph.D.		1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 February 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,25,28,31,53,77,80,83 and 87-97 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,25,28,31,53 and 87-95 is/are rejected.
- 7) ☒ Claim(s) 77, 80, 83, 96, 97 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt is acknowledged of a reply to the previous Office Action, filed February 21, 2007. Claims 10, 26, 27, 30, 62, 78, 79 and 82 were canceled. Claims 91-97 are added.

Claims 1, 25, 28, 31, 53, 77, 80, 83 and 87-97 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed August 22, 2006, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 25, 28, 31 and 91-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the biological substance" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim.

#### ***Claim Rejections - 35 USC § 102***

A person shall be entitled to a patent unless –

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 53, 87, 88, 89 and 90 stand rejected under 35 U.S.C. 102(e) as being anticipated by US 6,361,973. New claims 92-95 are also rejected under 35 U.S.C. 102(e) as being anticipated by US 6,361,973. Since new claims are added to the rejection, the rejection is repeated below with the new and amended limitations incorporated. Response to Applicants' arguments follows.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Applicants claim a method for producing a polypeptide comprising cultivating a fungal host cell that comprises one copy of a first nucleic acid sequence encoding the biological substance operably linked to a second nucleic acid sequence comprising a

promoter variant comprising SEQ ID NO: 5, a subsequence, a hybrid promoter, or a tandem promoter, and isolating the polypeptide. The subsequence and hybrid promoter comprise at least one copy of SEQ ID NO: 70. The polypeptide is a hormone, enzyme or receptor, and is native or foreign to the host cell. Specifically, applicants teach a method for producing a polypeptide comprising cultivating a fungal host cell that comprises one copy of a first nucleic acid sequence encoding the biological substance operably linked to a second nucleic acid sequence comprising a tandem promoter, and isolating the polypeptide. Also claimed is the promoter variant of SEQ ID NO: 5, subsequences thereof, and hybrid promoters thereof, a nucleic acid construct encoding the biological substance operably linked to a second nucleic acid sequence comprising a promoter variant, SEQ ID NO: 5, a subsequence, a hybrid promoter, a tandem promoter, a vector comprising the nucleic acid construct, and a host cell comprising the nucleic acid construct. The subsequence and hybrid promoter comprise at least one copy of SEQ ID NO: 70. Lastly, a method for producing a biological substance comprising a recombinant cell comprising a promoter variant, an exon, and/or a splice donor site operably linked to a second exon encoding the biological substance and recovering the substance, is claimed.

US 6,361,973 (specifically abstract, columns 1, 2, 10 and 11, claim 1 and SEQ ID NO: 1) teach a method for producing a polypeptide comprising cultivating a fungal host cell that comprises a first nucleic acid sequence encoding a polypeptide operably linked to a second nucleic acid sequence comprising a promoter, SEQ ID NO: 1, subsequences, hybrid promoters, tandem promoters, and isolating the polypeptide.

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Specifically, US 6,361,973 teach a method for producing a polypeptide comprising cultivating a fungal host cell that comprises one copy of a first nucleic acid sequence encoding the biological substance operably linked to a second nucleic acid sequence comprising a tandem promoter, and isolating the polypeptide. SEQ ID NO: 5, a subsequence, a hybrid promoter, and a tandem promoter are listed in the alternative. There is no requirement for the tandem promoter to contain a copy of SEQ ID NO: 70. Therefore, all that is needed is a method for producing a polypeptide comprising cultivating a fungal host cell that comprises one copy of a first nucleic acid sequence encoding the biological substance operably linked to a second nucleic acid sequence comprising a tandem promoter, and isolating the polypeptide. Also taught is the promoter, SEQ ID NO: 1, subsequences, and hybrid promoters, and tandem promoters, a nucleic acid construct encoding the polypeptide operably linked to a second nucleic acid sequence comprising a promoter, tandem promoters, a vector comprising the nucleic acid construct, and a host cell comprising the nucleic acid construct. Lastly, a method for producing a polypeptide comprising a recombinant cell comprising a promoter variant, an exon, and/or a splice donor site operably linked to a second exon encoding the polypeptide and recovering the polypeptide, is taught.

#### **Response to Arguments Concerning Claim Rejections – 35 USC § 102(e)**

Applicant's arguments filed on February 21, 2007 have been fully considered. The following grounds of traversal are presented:

US 6,361,973 does not disclose a subsequence of SEQ ID NO: 5 comprising at least one copy of SEQ ID NO: 70, nor does it disclose a hybrid promoter comprising a portion of SEQ ID NO: 3 and a portion of SEQ ID NO: 5, wherein at least one of the portions comprises at least one copy of SEQ ID NO: 70.

Applicant's traversal has been fully considered and not found to be persuasive for the following reasons:

US 6,361,973 does not disclose a subsequence of SEQ ID NO: 5 comprising at least one copy of SEQ ID NO: 70, nor does it disclose a hybrid promoter comprising a portion of SEQ ID NO: 3 and a portion of SEQ ID NO: 5, wherein at least one of the portions comprises at least one copy of SEQ ID NO: 70. However, it does disclose a method for producing a polypeptide comprising cultivating a fungal host cell that comprises one copy of a first nucleic acid sequence encoding the biological substance operably linked to a second nucleic acid sequence comprising a tandem promoter, and isolating the polypeptide, as well as an isolated promoter variant comprising a tandem promoter, which is what is being claimed.

***Allowable Subject Matter***

Claims 77, 80, 83, 96 and 97 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele K Joike, Ph.D.  
Examiner  
Art Unit 1636

  
NANCY VOGEL  
PRIMARY EXAMINER